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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PANTUCK, BRADFORD C	
ART UNIT	**PAPER NUMBER**
3731	5

DATE MAILED: 11/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/080,787	RABINER ET AL.	
	Examiner	Art Unit	
	Bradford C Pantuck	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 6 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02/22/02* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4 only*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed February 2nd, 2002 fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office. It has been placed in the application file, but the information referred to therein has not been considered.

The information disclosure statement (IDS) submitted on June 20th, 2003 was filed and received by the examiner. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, this information disclosure statement is being considered by the examiner.

Specification

2. The abstract of the disclosure is objected to because the word "debris" is inherently plural, and cannot be referred to in the singular, as "a debris". Correction is required. See MPEP § 608.01(b).

Claim Objections

3. Claims 5, 17, and 26 are objected to because of the following informalities: the word "debris" is inherently plural, and cannot be referred to in the singular, as "a debris". Appropriate correction is required.

4. Claims 1 and 17 are objected to because of the following informality: in line 4 of Claim 1 and again in Claim 17, the Applicant uses the word "proximal," seemingly,

to refer to what is usually referred to as the "distal" end of the device—the end of the device furthest from the user.

Claim Rejections - 35 USC § 112

5. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the preamble, Applicant sets forth "A vascular introducer *for insertion into* a vascular access device comprising...". However, in line 5, Applicant says that the anchoring mechanism "*engages an inner surface of* the vascular access device..." It is unclear whether or not Applicant is intending to claim the vascular access device as part of his invention. The preamble implies that he is not, although line 5 suggests that he intends for the vascular access device to be a part of his invention. Note: if Applicant does not intend to include the vascular access device as part of his invention, he should instead say that the anchoring mechanism is "adapted to be engaged to an inner surface of the vascular access device..." or similar phrasing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-21 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,692,139 to Stiles. Regarding Claims 1, 2, and 9-12 Stiles discloses a vascular introducer for insertion into a blood vessel. His introducer has an elongated shaft (1) and an anchoring mechanism (5). The anchoring mechanism (5) has a retracted position [see Fig. 1] and an extended position [see Fig. 3] in which the anchor is able to engage the inner surface of the artery [Column 3, lines 54-57]. Were anchoring mechanism inserted through a hole in the wall of a vessel just bigger than the diameter of elongated shaft (1), and the anchoring mechanism (5) put into an extended position, when the user pulls proximally (to retract the device), anchoring mechanism (5) will resist this movement, being lodged inside the vessel. Even though anchoring mechanism (5) is disclosed as intended for a different use by Stiles (of catching fragments of debris), it will serve as an anchor, and is able to be used as an anchor. Stiles' anchoring mechanism (5) is made out of rubber [Column 3, lines 38-39], and is capable of *securing the introducer*, as it is capable of becoming *lodged within a vessel or a hole in a vessel.*

Stiles also discloses an activation mechanism (2/3) that moves the anchoring mechanism (5) from the retracted position to the extended position. With reference to Figure 3, Stiles explains that to activate the anchoring mechanism (5) into a retracted position, the user should turn tube 3, which will rotate the anchoring mechanism (5), and in conjunction with the cooperating threads on the inside of the shaft (1), will cause the anchoring mechanism (5) to move distally, into the retracted position

[Column 3, lines 30-39]. As explained in the preceding passage, the anchoring mechanism (5) is mounted on activating mechanism (3).

7. Regarding Claim 3, Stiles discloses a vascular introducer with an anchoring mechanism (5) that maintains contact between the vascular introducer and the blood vessel to prevent removal or detachment.

8. Regarding Claims 4 and 9, Stiles discloses a rotating mechanism that allows the vascular introducer to change direction within the blood vessel without being removed. By way of illustration, if one inserted the end of a pencil into a hole formed in a blood vessel, one *would be able to rotate it. There would be nothing preventing one from doing so*. The mechanism would merely be the end of the shaft (1), lubricated by the blood of the vessel. The absence of a protrusion, roughened section, or interfering component will allow the introducer (1) to be rotated.

Applicant does not claim any particular structure that does this, nor does he show in the pictures what such a mechanism should look like. Applicant discloses in the specification that the mechanism can be a ball-and-socket arrangement, a hinged arrangement, etc, but it is unclear how these mechanisms would function at the end of the device. Regardless, Applicant has not set forth any of these specific mechanisms *within the claims*.

9. Regarding Claims 5-7, and 13-15, Stiles discloses an ultrasonic probe (6), shown clearly in Figure 3, inserted through the vascular introducer (1) into the blood vessel for ablation of debris inside the vessel [Column 2, lines 46-63]. The debris is an

obstruction in the vessel [Column 2, lines 57-60] and is ablated by emitting ultrasonic energy [Column 1, lines 44-48].

10. Regarding Claims 8 and 16, the device is capable of being used once on a single patient and then discarded.

11. Regarding Claims 17-20, Stiles discloses a method of clearing debris from a blood vessel, including all of the mentioned steps. Stiles discloses placing the vascular introducer into the vascular access device, and ablating debris using the ultrasonic probe. The introducer need not be removed from the artery during ablation because a vacuum sucks the debris out through the tube (1) [Column2, lines 46-63].

12. Regarding Claim 21, Stiles discloses rotating the vascular introducer (1/3) within the vascular access device without removing the introducer 1/3) from the vascular access device. The introducer (1/3) is rotated relative to component (9) at its proximal end [Column 4, lines 37-41].

13. Claims 1-4, 8-12, and 16 are also rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,782,861 to Cragg et al. Regarding Claims 1, 2, and 9-12 Cragg discloses a vascular introducer for insertion into a blood vessel [Column 4, line 62 to Column 5, line 2]. His introducer has an elongated shaft (18) and an anchoring mechanism (42). The anchoring mechanism (42) has a retracted position [see Fig. 1] and an extended position [see Fig. 11] in which the anchor engages the inner surface of the artery [Column 7, lines 55-59].

Cragg also discloses an activation mechanism (62) that moves the anchoring mechanism (42) from the retracted position to the extended position. With reference to Figure 3, Cragg explains that to activate the anchoring mechanism (42) from the retracted position to the extended position, the user should push button (62) distally. Note that the anchoring mechanism (42) is attached to the end of shaft (38) [Column 5, lines 52-61].

14. Regarding Claim 3, Cragg discloses a vascular introducer with an anchoring mechanism (42) that maintains contact between the vascular introducer and the blood vessel to prevent removal or detachment [Column 7, lines 55-67]. Cragg grips the vessel tightly, having its hook shape end pierce the vessel. While the anchoring mechanism (42) is still attached to the shaft (38), the anchoring mechanism (42) will maintain contact between the vascular introducer and the blood vessel to prevent removal or detachment.

15. Regarding Claims 4 and 9, Cragg discloses a rotating mechanism that allows the vascular introducer to change direction within the blood vessel without being removed. The mechanism would merely be the end of the shaft (18), lubricated by the blood of the vessel. The absence of a protrusion, roughened section, or interfering component will allow the introducer (18) to be rotated.

As mentioned before, Applicant does not claim any particular structure that does this, nor does he show in the pictures what such a mechanism should look like. Applicant discloses in the specification that the mechanism can be a ball-and-socket arrangement, a hinged arrangement, etc, but it is unclear how these mechanisms

would function at the end of the device. Regardless, Applicant has not set forth any of these specific mechanisms *within the claims.*

16. Regarding Claims 8 and 16, Cragg's device is meant to be used once on a single patient and then discarded [Column 2, lines 28-34 and Column 9, lines 17-22].

17. Claims 17-23, 25-29, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,508,782 to Evans et al. Regarding Claims 17-20 and 27, Evans discloses a method of clearing debris from a blood vessel, including all of the mentioned steps. Evans discloses placing the vascular introducer into the vascular access device [Column 1, lines 21-25], and ablating debris using the ultrasonic probe [Column 5, lines 34-41]. The introducer need not be removed from the artery during ablation because a vacuum (102) sucks the debris out through the tube (10) [Column 8, lines 19-28]. The debris can be a blockage/occlusion [Column 3, lines 24-28].

18. Regarding Claims 21 and 26, Evans discloses rotating the vascular introducer (10) within the vascular access device without removing the introducer (10) from the vascular access device (55). The introducer (10) is rotated in order to help dislodge plaque on the inside of the vessel [Column 6, lines 45-59]. The arrows in Figure 9 illustrate the rotation of the catheter introducer (10).

19. Regarding Claims 22 and 28, Evans discloses a method of employing an anchor (120) that maintains contact between the vascular introducer and the blood vessel (55) to prevent removal or detachment of the introducer from the blood vessel [see Fig. 18]. As is obvious from the picture shown, the expanded filter trap (12) will not be

able to move proximally, because *it is trapped by the blockage (plaque 55) in the artery*. As is clearly shown in Figure 18, the anchor (120) expands to fill the whole artery, to the point of contacting the inner edges of the vessel. Additionally, the anchor may take the form shown in Figures 19 and 20, and will "seal against the vessel wall" [Column 11, lines 15-29]. Evans' anchor is not a permanent anchor, but neither are the embodiments disclosed in the Applicant's disclosure. None of the anchors disclosed by the Applicant (balloon 80, prongs 72, extensions 78) are permanent anchors, nor do any of the Applicant's become embedded in the vessel wall, as one generally thinks of an anchor doing. *Evans' anchor has all of the structure of the Applicant's anchors in the specification (expandable to fill the vessel, prevention—deterrence of removal) and will therefore be able to perform the same function as the Applicant's anchor.*

20. Regarding Claims 23 and 29, Evans' anchor is moveable between a retracted position and an extended position. The anchor (12) is shown in its extended position in Figure 17, and is described as being capable of being retracted into the catheter (10) [Column 10, lines 37-42].

21. Regarding Claims 25 and 31, Evans' device is *capable of being used* once on a single patient. It is well known to modern surgical/hospital/nursing practitioners that devices such as these, inserted into one patient's vasculature should not be used again on another patient because of common sense.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

22. Claims 5-7 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,782,861 to Cragg et al. in view of U.S. Patent No. 4,692,139 to Stiles. Cragg discloses the invention as claimed, including an electrocauterizing probe inserted through the elongated shaft (18), which is intended to help promote hemostasis. However, Stiles teaches that one can use an electrocauterizing probe, such as the one disclosed by Craggy, for removing obstructions in blood vessels. Stiles further explains that an even better means for removing these obstructions in blood vessels is to replace the electrocauterizing probe with an ultrasonic probe so that the surgery will be less traumatic. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to replace the electrocauterizing probe of Cragg with an ultrasonic probe in order to perform less traumatic removals of obstructions in blood vessels.

23. Claims 24 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,508,782 to Evans et al. in view of U.S. Patent No. 5,782,861 to Cragg et al. Evans discloses an anchor that moves from a retracted position to an extended position, but does not disclose a *specific mechanism* for making it perform this function. Assumedly, he extends the anchor by hand by sliding it through tube

(10). However, Cragg explains that to activate the an anchoring mechanism (42) from a retracted position to an extended position, there can be a *button* provided, which is intended for a human's thumb [Column 5, lines 52-61]. It would have been obvious to one having ordinary skill in the art at the time of the invention to include a mechanism, such as a thumb button, with Evans' device since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result requires only routine skill in the art.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 6,544,276 B1 to Azizi

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

BCP
BCP

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